

Certificate of Analysis


Certificate No.: **20250616005**

Date: June 16, 2025

Retest date: April 30, 2028

Compound Name: Elmustine	
Synonyms:	1-(2-chloroethyl)-3-(2-hydroxyethyl)-1-nitrosourea
TLC Catalogue Number:	E-133001
CAS Number:	60784-46-5
Alternate CAS Number:	N/A
Molecular Weight:	195.60
Molecular Formula:	C ₅ H ₁₀ ClN ₃ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	6753-073A8
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Acetonitrile

Test Description	Specifications	Results
Visual Description	Off-white solid	Conforms
Identification		
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.7%
Impurity (HPLC)	RT 5.90, 0.25%	
Water Content (KF)	N/A	0.2%
Residual Solvents (NMR)	0.1% ethyl acetate and 0.1% <i>n</i> -hexane	
Assay (%)	Not less than 90.0%	99.3%
Recommendation:	Release. The compound is a <i>N</i> -Nitroso product. Avoid using metal spatula and applying pressure. Wear proper personal protective equipment when handling. It contains 0.3% Elmustine Impurity 1 (RT 5.90, TLC No. E-133002) according to its HPLC.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/16/2025
Approved by:	Quality Assurance		06/16/2025

Attachments: Peak Attribution Table, HPLC, MS and NMR spectra.